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10/523,622	02/04/2005	Xinqi Liu	4439-4029	5866
27123 7590 09/03/2008 MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101				
EXAMINER DEES, NIKKI H				
ART UNIT 1794		PAPER NUMBER		
NOTIFICATION DATE 09/03/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/523,622

Applicant(s)

LIU ET AL.

Examiner

Nikki H. Dees

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 14, 2008, has been entered.
2. Claims 1 and 4-13 are currently pending in the application. Claims 2, 3 and 14-16 have been cancelled. The previous 35 USC 112 rejection of claim 11 has been withdrawn in view of the amendment to claim 11. The previous 35 USC 103 rejections of claims 1 and 4-16 have been withdrawn in view of the amendment to claim 1 and the cancellation of claims 14-16.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 13 recites the limitation "the isolation step" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claim 13 is dependent on claim 1.

Claim 1 has been amended and the isolation step has been replaced by a drying step. It is unclear if the sterilization step is still required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Amended claims 1, 4-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muralidhara et al. (6,630,195) in view of General Foods Corp. (JP 44-6211 B) and Koski et al. (3,653,912).

8. Muralidhara et al. ('195) teach a method for extracting oilseed material under basic conditions. The method comprises mixing an oilseed material with an aqueous alkaline solution, with pH of about 7.5 to 10. It is stated that the pH is allowed to slowly decrease as subsequent extractions occur (col. 7 lines 34-53). The method produces a mixture of insoluble material, including proteins, in the aqueous phase (col. 7 lines 61-

63). The method also comprises the use of multi-stage counter-current extractions to increase the efficiency of the extractions and produce and extract solution with a high concentration of dissolved solids (at least about 7%) (col. 8 lines 16-30).

9. Regarding claim 4 to the use of a three-stage counter-current extraction method, one of ordinary skill in the art would have the ability to adjust the number of stages in the counter-current extraction in order to provide for the most efficient protein recovery while keeping associated costs low. A three-stage counter current extraction method is specifically taught in Fig. 5. of '195 (AT-101, AT-102 and AT-103).

10. Regarding claim 6, the '195 patent teaches that the aqueous solution is present in a ratio ranging from 6:1 to 10:1 of the oilseed material (col. 8 lines 22-24). This range overlaps that claimed by Applicant, rendering Applicant's range *prima facie* obvious.

11. Regarding claim 7, the '195 patent teaches the temperature range for the extraction at about 15 to 40°C (col. 7 lines 9-12). This is within the range as claimed by Applicants.

12. Regarding claim 13, the '195 patent teaches pasteurization and spray drying to separate the water and protein in the isolation step (col. 16 lines 3-12).

13. The '195 patent is silent as to the use of acid-washed protein flakes in their process and directly drying the protein following the alkali extraction step. They also do not state the starting protein content of their extraction process.

14. General Foods Corp. teach a process for acid washing soy-protein flakes in order to solubilize components such as carbohydrates and salts, followed by adjusting the flake slurry to a neutral to alkaline pH to solubilize the soy protein (pp. 3-4).

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15. As both the '195 patent and General Foods teach a method for removing components other than soy protein from the processing stream (the '195 patent by filtration, General Foods by acid washing) it would have been obvious to one of ordinary skill in the art to achieve the predictable result of removing components other than soy protein by acid washing as taught by General Foods before subjecting the soy protein to the counter-current extraction process of the '195 patent.

16. Regarding the spray-drying step, Koski et al. ('912) teach a method for modifying soy protein wherein the protein is kept above the isoelectric point and therefore remains in solution (col. 2 lines 8-10). The soy protein is then used directly from solution, or may be spray-dried (col. 2 lines 59-65).

17. As the teachings of the '195 patent, General Foods and the '912 patent were all known in the prior art at the time the invention was made, one of ordinary skill in the art would have been able to combine the acid-washing steps of General Foods with the alkali extraction of the '195 patent and the spray-drying directly from solution of the '912 patent in order to achieve the predictable result of an acid-washed, alkaline-extracted, spray-dried soy protein.

18. Regarding claim 8 and the protein content of the extract solution, the concentration of soy protein in the extraction solution as taught by the '195 patent is lower than that claimed by Applicants (col. 8 lines 49-53). One of ordinary skill would expect the method of the '195 patent in view of General Foods Corp. to result in a higher protein content due to a lower amount of non-protein material present in the extract.

19. Regarding claim 10 and the multi-stage acid washing of the soy protein, acid washing the soy protein more than once is considered obvious over the teachings of General Foods as the repeated washings result in a product with the same utility as the singly-washed product in of General Foods.

20. Regarding claim 11 and the crude-protein content of the material after the acid-washing step, General Foods Corp. do not report the crude protein content after the acid-washing step. Given that the starting material for both the claimed method and the method of General Foods Corp. is the same, it would be expected that the crude protein content after the acid washing steps would also be the same.

21. Regarding the gel strength of the isolated soy protein, the gel strength taught by the '195 patent is lower than that claimed by Applicants (col. 17 lines 48-51). However, the conditions reported for the gel strength are not the same. It would be expected that the soy protein isolate produced by the process of the '195 patent in view of General Foods Corp. and the '912 patent would have a gel-strength as claimed by Applicants.

22. Amended claims 1, 4-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muralidhara et al. (6,630,195) in view of O'Connor (3,586,662) and Koski et al. (3,653,912).

23. Muralidhara et al. ('195) teach a method for extracting oilseed material under basic conditions. The method comprises mixing an oilseed material with an aqueous alkaline solution, with pH of about 7.5 to 10. It is stated that the pH is allowed to slowly decrease as subsequent extractions occur (col. 7 lines 34-53). The method produces a

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mixture of insoluble material, including proteins, in the aqueous phase (col. 7 lines 61-63). The method also comprises the use of multi-stage counter-current extractions to increase the efficiency of the extractions and produce and extract solution with a high concentration of dissolved solids (at least about 7%) (col. 8 lines 16-30). Oilseed materials taught for use in the invention include soybean meal and sunflower meal (col. 6 lines 40-46).

24. Regarding claim 4 to the use of a three-stage counter-current extraction method, one of ordinary skill in the art would have the ability to adjust the number of stages in the counter-current extraction in order to provide for the most efficient protein recovery while keeping associated costs low. A three-stage counter current extraction method is specifically taught in Fig. 5. of '195 (AT-101, AT-102 and AT-103).

25. Regarding claim 6, the '195 patent teaches the aqueous solution is present in a ratio ranging from 6:1 to 10:1 of the oilseed material (col. 8 lines 22-24). This range overlaps that claimed by Applicant, rendering Applicant's range *prima facie* obvious.

26. Regarding claim 7, the '195 patent teaches the temperature range for the extraction at about 15 to 40°C (col. 7 lines 9-12). This is within the range as claimed by Applicants.

27. Regarding claim 13, the '195 patent teaches pasteurization and spray drying to separate the water and protein in the isolation step (col. 16 lines 3-12).

28. The '195 patent is silent as to the use of acid-washed protein flakes in their process and directly drying the protein following the alkali extraction step. They also do not state the starting protein content of their extraction process.

29. O'Connor ('662) teaches a process for multi-stage acid washing of defatted oilseed material (sunflower meal) in order to minimize coloration of the final product, followed by alkali extraction. The protein isolate is then recovered by acid precipitation or other protein recovery method, resulting in a protein isolate (col. 2 lines 30-40).

30. As both the '195 and '662 patents teach a method for preparing protein isolates from oilseed materials, it would have been obvious to one of ordinary skill in the art to achieve the predictable result of removing components other than soy protein by acid washing as taught by the '662 patent before subjecting the soy protein to the counter-current extraction process of the '195 patent. Further, this acid washing would have been expected to improve the process of the '195 patent as it would have reduced the contaminants of the protein-containing solution.

31. Regarding the spray-drying step, Koski et al. ('912) teach a method for modifying soy protein wherein the protein is kept above the isoelectric point and therefore remains in solution (col. 2 lines 8-10). The soy protein is then used directly from solution, or may be spray-dried (col. 2 lines 59-65).

32. Regarding claim 8 and the protein content of the extract solution, the concentration of soy protein in the extraction solution as taught by the '195 patent is lower than that claimed by Applicants (col. 8 lines 49-53). One of ordinary skill would expect the method of the '195 patent in view of the '662 patent to result in a higher protein content due to a lower amount of non-protein material present in the extract.

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33. Regarding claim 10 and the multi-stage acid washing of the soy protein, the '662 patent teaches washing the oilseed material from 2-7 times (col. 3, lines 56-58). This range encompasses that claimed by Applicants.

34. Regarding claim 11 and the crude-protein content of the material after the acid-washing step, the '662 patent does not report the crude protein content after the acid-washing step. However, given that the acid washing step as taught by the '662 patent is the same as that claimed by Applicants, absent any convincing arguments or evidence to the contrary, one of ordinary skill would have a reasonable expectation that employing another oilseed material such as soybean meal in the method of the '662 patent would result in a protein content following the acid washing steps as claimed by Applicants. Further, one of ordinary skill in the art at the time the invention was made would have been able to repeat the washings to achieve the desired protein content. This optimization would require nothing more than routine experimentation on the part of the artisan.

35. As the teachings of the '195, '662, and '912 patents were all known in the prior art at the time the invention was made, one of ordinary skill in the art would have been able to combine the acid-washing steps of the '662 patent with the alkali extraction of the '195 patent and spray-drying directly from solution of the '912 patent in order to achieve the predictable result of an acid-washed, alkaline-extracted, spray-dried soy protein.

36. Regarding the gel strength of the isolated soy protein, the gel strength taught by the '195 patent is lower than that claimed by Applicants (col. 17 lines 48-51). However,

the conditions reported for the gel strength are not the same. It would be expected that the soy protein isolate produced by the process of the '195 patent in view of the '662 and '912 patents would have a gel-strength as claimed by Applicants.

37. Amended claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muralidhara et al. (6,630,195) in view of O'Connor (3,586,662), Koski (3,653,912) and Gomi et al. (4,186,218).

38. The combination of the '195, '662 and '912 patents teaches a method for producing an isolated soy-protein as detailed above with regard to claim 1.

39. The combination is silent as to the use of an emulsifier in the acid-washing step.

40. Gomi et al. ('218) teach the use of an emulsifier including glycerin fatty acid esters to act as surface active agents in the processing of soybean flake material (col. 3 lines 7-12).

41. One of ordinary skill in the art at the time the invention was made would have known the effects of adding an emulsifier (surface active agent) to a solution of soy protein. The addition of the surface active agent as taught by the '218 patent in the acid-washing step of the '662 patent would have been expected to increase the solubility of the soy protein in order to improve the efficiency of the acid washing step. This would have been a predictable result, obtainable with nothing more than routine experimentation by one of ordinary skill in the art.

Response to Arguments

42. Applicant's arguments filed July 14, 2008, have been fully considered and are persuasive with regard to the previously presented rejections when applied to the amended claim 1. A new grounds of rejection is presented *supra* to incorporate Applicant's amendment to claim 1 requiring directly drying the extract solution obtained in the extraction step.

43. Applicant argues (Remarks, pp. 6-11) that the combination of Muralidhara in view of General Foods does not teach the invention as claimed in the amended claim 1.

44. A new grounds of rejection has been presented to incorporate a third reference, Koski et al. (3,653,912) wherein an extract solution of soy protein is spray-dried directly, without an intermediate acid-precipitation step. The combination of references as presented above is considered to render the claimed invention obvious over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-5:00 EST (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nikki H. Dees
Examiner
Art Unit 1794

/Carol Chaney/
Supervisory Patent Examiner, Art Unit 1794